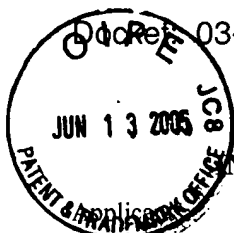


1FW



03-278US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/664,601  
Date Filed: 09/18/2003  
Title: SOLID OR SEMI-SOLID THERAPEUTIC FORMULATIONS  
Group Art Unit: 1615  
Examiner.: Thurman K. Page  
Atty. Docket: 03-278US1

INFORMATION DISCLOSURE STATEMENT (IDS)

Mail Stop Amendment  
Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

SIR:

In accordance with 37 C.F.R. §1.56 and in compliance with 37 C.F.R. §§1.97 and 1.98, the references listed on attached Form PTO/SB/08 and/or subsequently identified herein, are being submitted herewith for consideration by the United States Patent and Trademark Office.

I. COPIES

- a. ☒ A legible copy of (i) each foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed, is included herewith.
- b. ☐ Any patents, publications or other information which are listed on PTO/SB/08 which are not enclosed herewith were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. §120:

U.S. Serial Number

U.S. Filing Date

II. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)

- a. ☒ Except as may be indicated below in (b) of this section, all of the patents, publications or other information are in the English language (concise explanation not required).
- b. ☐ A concise explanation of the relevance of all patents, publications or other information listed that is not in the English language is as follows:
- c. ☐ The following additional information is provided for the Examiner's consideration:

III. ☐ CROSS REFERENCE TO RELATED APPLICATION(S)

The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this (these) applications to the Examiner's attention, Applicant(s) does(do) not waive the confidentiality provisions of 35 U.S.C. §122.

Serial No.

Filing Date

Art Unit

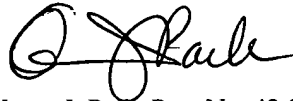
**FEES**

- IV. ☒ THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(b): (check one box)
- a. ☐ within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) (37 C.F.R. §1.97(b)(1)). No fee or statement is required.
  - b. ☐ within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. §1.97(b)(2)). No fee or statement is required.
  - c. ☒ before the mailing date of a first Office Action on the merits (37 C.F.R. §1.97(b)(3)). No fee or statement is required.
  - d. ☐ before the mailing date of a first Office Action after the filing of a request for continued examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.
- V. ☐ THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(c): (check one box)
- before the mailing date of any of a Final Office Action under 37 C.F.R. §1.113, a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application (See 37 C.F.R. §1.97(c)).
- a. ☐ No statement; therefore, charge deposit account 50-1047 the fee set forth in 37 C.F.R. §1.17(p).
  - b. ☐ See the statement below. No fee is required.
- VI. ☐ THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(d):
- on or before payment of the issue fee and is accompanied by the following:
- 1) a statement under 37 C.F.R. §1.97(e) as provided below; and
  - 2) charge deposit account 50-1047 the petition fee set forth in §1.17(p).
- VII. ☐ STATEMENT UNDER 37 C.F.R. §1.97(e) (check only one box, if applicable)
- The undersigned hereby states that
- a. ☐ each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of IDS; or
  - b. ☐ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and to knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement, or
  - c. ☐ some of the items of information contained in the IDS were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement.
- VIII. PAYMENT OF FEES
- ☐ A check in the amount of \_\_\_\_\_ is enclosed for the above-identified fee(s).
  - ☐ Please charge Deposit Account No. 50-1047 in the amount of \$180.00 for the above-indicated fee(s).
  - ☒ If Applicant has overlooked any additional fees, or if any overpayment has been made, the Commissioner is hereby authorized to credit or debit Deposit Account 50-1047.
  - ☐ Two Copies of this paper are attached for Deposit Account charges and debits.

It is Applicant(s)' opinion that the claims presently on file patently distinguish the present invention from each of these references. The above references are being cited only in the interests of candor and without any admission that they constitute statutory prior art or contain matter which anticipates the invention or which would render the same obvious, either singly or in a combination, to a person of ordinary skill in the art.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 50-1047.

Respectfully submitted,



Keum J. Park Reg. No. 42,059  
Attorney for Applicant(s)

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Customer Number 27774

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Enclosures:

☒  
☒  
☐  
☐


PTO/SB/08  
References (excluding U.S. patent documents)  
Foreign Search Report  
Other:

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 1

**Complete if Known**

Application Number	10/664,601
Filing Date	09/18/2003
First Named Inventor	Weenna Bucay-Couto
Group Art Unit	1615
Examiner Name	Thurman K. Page
Attorney Docket Number	03-278US1

Examiner Initials*	Cite No. 1	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Class/Subclass		
	1	6,495,164 B1	424/489	Ramstack et al.	12-17-2002
	2	4,927,806 A	514/2	Kramer et al.	05-22-1990

Examiner Initials*	Cite No. 1	U.S. Patent Applications		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Class/Subclass		
	1	2003/064998 A1	514/259.41	Francois et al.	04-03-2003

Examiner Initials*	Cite No. 1	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T
		Office <sup>3</sup>	Number <sup>4</sup>	Class/Subclass			
	1	EP	1 197 208 A1	A61K 9/52	Takeda Chemical Industries Ltd	04-17-2002	
	2	EP	1 078 636 A1	A61K 31/715	Zhao	02-28-2001	
	3	GB	811,717	A61k	Pfizer & Co., Inc.	04-08-1959	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>12</sup>Unique citation designation number. <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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